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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,383	03/04/2002	Maria Laura Gennaro	07763-043001	7070
26211 7590 10/18/2007 FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/009,383	GENNARO, MARIA LAURA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/07</u>                                                    | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 7 August 2007, is acknowledged. Claims 1, 2, 7, 8, 9, and 10 have been amended.
2. Claims 1-10 and 35 are pending and under consideration.

### **Rejection Withdrawn**

### **Rejections Maintained**

3. The rejection of claims 1-10 and 35 under 35 U.S.C. 103(a) as being unpatentable over Reed et al (WO98/16645, 23 April 1998), is maintained for reasons of record.

Applicant argues that the '645 application does not disclose or even remotely suggest that the MTBN4 polypeptide not be encoded by the genome of BCG. For example, in this regard, while the inventors of the '645 application were clearly cognizant of the fact that diagnostic assays available at the filing date of the '645 application could not distinguish between infection by *M. tuberculosis* and vaccination with BCG (see, for example, page 2, lines 2-3), nowhere in the '645 application is it suggested that any of the polypeptides it discloses, let alone the one with the amino acid sequence of MTBN4, could be used to distinguish exposure to *M. tuberculosis* from exposure to BCG without exposure to *M. tuberculosis*. For example, none of the experiments described in the '645 application compared subjects known to have been infected with *M. tuberculosis* to those that had been vaccinated with BCG and not been infected with *M. tuberculosis*.

BCG is derived from *Mycobacterium bovis*, the genome of which does encode MTBN4. Thus, in the absence of information to the contrary, one ordinarily skilled in the art would consider it likely that MTBN4 was also encoded by the genome of BCG. In addition, the '645

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application contains no teaching that would motivate one ordinarily skilled in the art to test whether it is encoded by the genome of BCG. Moreover, given the state of the art at the priority date of the instant application, even if such an artisan had by some remote chance been motivated to test for the possibility that MTBN4 might not be encoded by the genome of BCG, he or she would not have had a reasonable expectation of success. Clearly, it would not have been mere "common sense" to have tested for the possibility.

The examiner has considered applicants' argument, but does not find it persuasive because the claims are drawn to a product only. The claimed composition of claims 1, 2, 7-10 and 35 are drawn to "an isolated DNA molecule consisting of a DNA sequence encoding polypeptide MTBN4, or a segment shorter than full-length polypeptide MTBN4".

Applicant's statements, *supra*, actually state that polypeptide MTBN4 **is** encoded by the genome of BCG strain of *M. bovis*. This is a contradiction to the newly inserted wording which says that polypeptide "is not encoded" by the genome of BCG strain of *M. bovis*.

Until such time as applicant can explain this contradiction, the rejection remains because the cited reference does teach the polypeptide MTBN4 sequence and as stated in the original rejection explanation, because the protein sequence was known, it would have been obvious to one of ordinary skill in the art to instantly envision a DNA which encodes the known amino acid sequence.

### **New Rejection Necessitated by Amendment**

#### **Claim Rejections - 35 USC § 112**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-10 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, the claims are drawn to a DNA molecule consisting of a DNA sequence encoding polypeptide MTBN4, or a segment shorter than full-length polypeptide MTBN4, wherein the polypeptide is not encoded by the genome of cells of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*.

However, as evidenced by the sequence search, and applicant's own statements, *supra*, the polypeptide MTBN4 **is** encoded by the genome of BCG strain of *M. bovis*. Thus, it is unclear what, if any, differences are present in the claimed DNA and that of non-BCG DNA encoding the exact same amino acid sequence.

### Conclusion

6. No claims are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting Supervisor, Bruce Campell, can be reached on (571)272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

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October 15, 2007